

### REMARKS

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.112, are respectfully requested in light of the remarks which follow.

As set forth in the Office Action Summary, claims 1-3 and 5-24 are pending. Claims 13-16 stand withdrawn.

#### ***Rejections Under 35 U.S.C. §103***

Claims 1-3, 5-12, and 17-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Winkler et al. (Journal of Virology, 1997, 71:6727-6741) ("Winkler") and ter Meulen et al. (U.S. Patent No. 5,646,032) ("ter Meulen"). The Office states that the skilled artisan would refer to construction of foamy virus vectors as taught by ter Meulen et al. and could use the detailed sequence information in Winkler et al. to construct FeFV. Applicants respectfully traverse.

For a *prima facie* case of obviousness, the following three requirements must be met. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine the reference with another reference. Second, the proposed modification must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Third, the prior art reference must teach or suggest all the limitations of the claims. The teachings or suggestions as well as the expectation of success must come from the prior art and not from applicant's disclosure. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991); and *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Applicant respectfully submits that these criteria have not been met in the present Office Action in combining Winkler and ter Meulen.

Applicants submit that the cited references, taken together, fail to recite each element of the present invention, and that the skilled artisan would not combine them to arrive at the claimed vector with an expectation of success. First, ter Meulen

discloses that it is a requirement to first obtain an infectious molecular viral clone (pHSRV) from which foamy virus vectors are derived (see col. 2, lines 10-15 and col. 7, line 66 to col.8, line 15). ter Meulen fails to teach or to suggest how the skilled artisan may obtain an infectious Feline foamy virus clone.

Winkler discloses the deduced sequence of a Feline foamy virus, and only discloses non-Infectious subgenomic FeFV clones. Because Winkler only discloses non-infectious sub-genomic clones, the skilled artisan cannot expect that a full-length FeFV clone could be infectious.

As set forth in the present invention, clones containing the full-length proviral DNA does not efficiently provide the replication virus, as an additional substitution of a 4.2 kbp fragment was necessary to obtain a suitable infectious FeFV clone (see page 12, 1st full paragraph of the present specification). Thus, the sequence information of Winkler (the full length sequence) is not sufficient to make a suitable FeFV clone. Winkler would then requires a further step to achieve a suitable infectious FeFV clone from a full-length clone Thus, Applicants submit that Winkler does not disclose the necessary infectious FeFV clone or suggest it by merely reciting the full length sequence, as asserted by the Office.

The two references, taken in combination, do not teach or suggest the complex cloning steps needed to obtain an infectious FeFV clone from which FeFV vectors can be derived.

On page 5 of the outstanding Office Action, the Office states that it "appears that the sequence of the clone of claim 8 which is taught in Example 1 that results in the deposited pFeFv-7 is the same cloned viral sequence as the fully described clone of Winkler et al." Applicants submit this is not the case. The sequence of the infectious clone pFeFV-7 of claim 8 which is taught in Example 1 is not the same as the fully described sequence of Winkler. In support, Applicants submit a reference by Zemba et al. (*Virology*, 266, 150-156:2000). Zemba et al. compare the sequences of the pFeFV-7 clone and of that of Winkler. The sequence alterations of the pFeFV-7 clone are shown at page 151, right column, 1st paragraph (note that these alterations are also shown in Fig. 2 of the application). Thus, the sequence of the pFeFV-7 clone is distinct from the sequence of Winkler, and, therefore, Winkler does not disclose or even suggest an infectious clone. Further, knowing the full-

length sequences and having the partial clones of Winkler does not provide the teaching and motivation to create a FeFV clone, as required by the replication-competent or replication-incompetent vectors of the present invention

In summary, Applicants submit that the present claims are not obvious in view of the combined references, because clones of the first generation containing the full-length sequence of Winkler are not infectious, and ter Meulen fails to teach how to modify that first generation clones containing a full-length proviral DNA to obtain a functional and fully infectious FeFV clone from which replication-competent or replication-incompetent FeFV vectors could be derived.

### **CONCLUSION**

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this Amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

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